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JUL 5 2002

Allegiance

XIII. STATEMENT OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
POWDER-FREE LATEX EXAMINATION GLOVES
WITH COLORANTS

Manufacturer:	Allegiance Healthcare Corporation 1500 Waukegan Road, Bldg. WM McGaw Park, Illinois USA 60085
Regulatory Affairs Contact:	Erica Sethi 1500 Waukegan Road, Bldg. WM McGaw Park, IL 60085
Telephone:	(847) 785-3337
Date Summary Prepared:	February 12, 2002
Common Name:	Patient Examination Glove
Classification:	Glove, Examination (Latex)
Predicate Devices:	Polymer Coated Powder-Free Latex Examination Gloves With Protein and Chemotherapy Labeling Claim
Description:	Powder Free Examination Gloves are formulated using latex and have colorants. These gloves are offered non-sterile.
Intended Use:	Powder-Free Latex Examination Gloves are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner. These gloves contain 50 micrograms or less of total water extractable protein per gram. These gloves have been tested for use with chemotherapy drugs.

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XIII. STATEMENT OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (con't)
POWDER-FREE LATEX EXAMINATION GLOVES
WITH COLORANTS

Substantial Equivalence	Powder Free Examination Gloves with colorants are substantially equivalent to Polymer Coated Powder-Free Latex Examination Gloves in that they provide the following characteristics: - intended use - design, product features - made of natural rubber latex - physical characteristics

Summary of Test Results:

Test	Result
Primary Skin Irritation	Glove does not display irritation potential.
Guinea Pig Maximization	Glove does not display sensitization potential.
Ultimate Elongation & Tensile Strength	Glove meets or exceeds requirements for rubber examination gloves per ASTM D3578-01.
Barrier Defects	Glove exceeds requirements per 21 CFR §800.20 and ASTM D3578-01, AQL=2.5.
Powder Level	Glove meets powder level requirements for "Powder Free" designation per ASTM D 3578-01.
Protein Labeling Claim	Glove meets requirements for protein claim of 50 microgram or less of total water extractable protein per gram of glove using the ASTM Lowry test method (ASTM 5712-99).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 5 2002

Ms. Erica Sethi
Manager, Regulatory Affairs
Allegiance Healthcare Corporation
1500 Waukegan Road, Building WM
McGraw Park, Illinois 60085

Re: K020818
Trade/Device Name: Powder-Free Brown Latex Examination Glove (Tested for Use With Chemotherapy Drugs) with Protein Content Labeling Claim (50 Micrograms or Less)
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: April 15, 2002
Received: April 18, 2002

Dear Ms. Sethi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2460

Applicant: Allegiance Healthcare Corporation

510(k) Number: K020818

Device Name: Powder-Free Brown Latex Examination Glove (Tested For Use With Chemotherapy Drugs) With Protein Content Labeling Claim (50 micrograms or less)

Indications For Use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. This latex glove contains 50 micrograms or less of total water extractable protein per gram. In addition, this glove has been tested for use with chemotherapy drugs.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020818